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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,011

03/25/2004

Palpu Pushpangadan

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23973 7590 01/16/2007

DRINKER BIDDLE & REATH  
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,011	<b>Applicant(s)</b> PUSHPANGADAN ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-15,32-37 and 39-47 is/are rejected.
- 7) ☒ Claim(s) 7 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This Office Action is in response to the Amendment filed October 20, 2006. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Examiner acknowledges the withdrawal of the election of species requirement.

### *Claims*

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 1-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914) and Thiebaud (FR 2 509 609). The rejection is maintained in regards to claims 1-6 and 8-15 and withdrawn in regards to claims 7, 13 and 16.

Applicant argues the references of Thiebaud and Melman lack any teaching or motivation to combine constitutes with those features of Applicant's claims. The Examiner cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the invention. The references present a mere "invitation to explore" various combinations or additives but such an invitation does not obviate Applicants' pending claims. Farooqi does not suggest the desirability of combining *Azadirachta indica* with anything and discloses rice husk as a constituent of conventional tooth powders but goes further to term these compositions as not effective and even harmful for gums and teeth. The reference does not suggest or teach *Citrus*

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*karna* and the references themselves, must suggest the desirability or obviousness of making the combination without the slightest recourse to the teaching of Applicant's disclosure. Lawlor does not disclose, teach or even suggest the specific use of *Citrus karna*, nor does the reference provide any motivation to combine *Citrus karna* with *Zanthoxylu armatum*, *Azadirachta indica* or *Oriza sativa*. The arguments are not persuasive.

Withdrawn claim 16 provides conditions for which the compositions may be used. Each component set forth by the instant claims has a particular function. Therefore if one of ordinary skill in the art desired to treat each one of these conditions with one composition, it would be obvious to add an active agent that functions to treat the desired conditions. It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). *In re Dial* upheld the rejection made by the Examiner and confirmed by the Board of Appeals based on three references holding it would have been obvious to one of ordinary skill in the art to have combined four compounds from the three reference to make one composition. Farooqi discloses three of the components used in the instant invention and even disclose a composition comprising two of the essential components of the instant claims. Although Farooqi makes the statement "not effective and even harmful for gums and teeth", it

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does not mean all the components in previous tooth powders are harmful or not effective. If the rice husk used in the compositions were harmful or ineffective, it would not be a "conventional component" of tooth powders and it would be obvious to use "conventional components" when making a tooth powder. In regards to the *Citrus karna*, Lawlor uses *Citrus aurantium* (bitter orange) as one of the citrus species that may be used in the compositions. *Citrus karna* is a part of this species but is known as khatta, which is *Citrus karna*, in India<sup>1</sup>. In regards to the synergistic effect of the compositions, Applicants do not appear to point out unexpected results as expected by the use of the term "synergistic". Applicant also does not appear to show how the combination of these particular components differs from a combination of components with the corresponding functionalities disclosed in the prior art. For example, Applicant argues the *Citrus karna* is not proven by the Office to have the same effect as those citrus compounds disclosed in Lawlor, yet Applicant does not make a showing of how using another type of citrus effects the compositions. Applicant also does not show replacing any other of the essential ingredients with compounds that have the same functionalities to show their effects to distinguish those of the instant claims from those of the prior art. See *In re Kollman and Irwin*, 201 USPQ 193 (C.C.P.A. 1979).

2) Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914) and Thiebaud (FR 2

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<sup>1</sup> <http://pick4.pick.uga.edu/mp/20q?search=Citrus+aurantium&guide=Trees> Morton, J. 1987. Sour Orange. p. 130-133. In: Fruits of warm climates. Julia F. Morton, Miami, FL. Page 4 of 11

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509 609) as applied to claims 1-13 and 16 above, and further in view of Melman (US 2002/0156130). The rejection is maintained.

See Applicant's arguments and Examiner's response above.

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)**

1) Claims 32-37 and 39-43 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914).

Farooqi et al. disclose dental compositions, mainly tooth powders for treatment of pyorrhea, yellowing/staining of teeth and sensitivity. The compositions comprise *Zanthoxylum armatum*, which is useful for toothaches. It comprises from 20 to 25% of the composition. The powder of *Zanthoxylum armatum* is obtained from its flowers, leaves, roots or fruits, as in claim 36. The composition also comprises an antiseptic, a compound to improve odor, a fragrance and an astringent. The reference also list common ingredients used in toothpowders found in India. They include *Azadirachta indica*, which has antiseptic and analgesic action (col. 3, lines 19-24). It can be assumed the *Azadirachta indica* is a powder because it is incorporated into a tooth powder and it originates from twigs, as in claim 37. Also used in toothpowders is rice husk, which is also *Oriza sativa* (col. 4, table). The antiseptic used in the disclosed compositions was *Zingiber officinale* at a concentration of 25 to 30% of the composition. The reference differs from the instant claims insofar as it does not disclose using

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*Zanthoxylum armatum* in combination with *Citrus karna*, *Azadirachta indica* and *Oryza sativa*.

Lawlor teaches oral compositions that comprise an effective amount of an antibacterial seed or pulp extract from the Citrus plant family (paragraph 0002). These compositions are used to treat halitosis as in claim 32. The products are prepared in stable confectionery forms and portable oral care, which provides comparable benefits to frequent brushing. These forms include toothpaste, dentifrice, mouthwash or mouth rinses, topical oral gels, denture cleanser, mouth spray, dental floss, confectionery including chewing gum and lozenge, and the like, as recited in claim 33. When the plant extracts are in conjunction with other anti-plaque agents the combination results in a greater plaque reduction than would be seen with either active alone. The citrus extracts also have malodor benefits (paragraph 0012). When combined with a metal, they improve the malodor benefits of the composition (paragraph 0014). Decrease in hypersensitivity occurs when citrus extracts are used in combination with hypersensitivity agents (paragraph 0013). The citrus extract may comprise from 0.0001 to about 30% of the oral composition, which encompasses the instant claims, and are obtained from the seed or pulp, encompassing claim 35. The compositions also comprise an oral care active selected from the group consisting of anti-calculus agents; anti-plaque agents; fluoride ion source; desensitizing agents; oral malodor control agents; and mixtures thereof; and a pharmaceutically acceptable carrier. The compositions may comprise ethanol as a warming agent and peppermint oil as a flavoring agent, which encompasses claims 40-42. Flavorings used include orange and

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lemon (paragraph 0129), which encompasses claim 46. Silica abrasives may also be used in the compositions with a particle size ranging from 0.1 to 30 microns (paragraph 0093), encompassing claim 43. Antibacterial extracts, which contain organic acids (0045), and anti-calculus components include acetic acids such as ethylenediaminetetraacetic acid are also used in the compositions (paragraph 0058). Although the reference does not specifically name *Citrus karna*, it list examples of various citrus plants that may be used and also discloses any citrus plant may be used in the compositions, such as *Citrus aurantium* (bitter orange), which is called khatta in India (or *Citrus karna*) see arguments above. The reference differs from the instant claims insofar as it does not disclose using citrus extract in combination with *Zanthoxylum armatum*, *Azadirachta indica* and *Oryza sativa*.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have added *Citrus karna*, *Azadirachta indica* and *Oryza sativa* in the toothpastes of the primary reference motivated by the desire to produce a toothpaste or toothpowder with the additive effects of treating toothaches with *Zanthoxylum armatum*, treating bad breath and adding flavoring with *Citrus karna* and killing germs



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and treating pain with *Azadirachta indica*, as taught by the combined references and supported by cited precedent.

2) Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914) as applied to claims 32-37 and 39-43 and 46-47 above, and further in view of Melman (US 2002/0156130).

The combined references are discussed above. The combined references differ from the instant claims insofar as they do not teach using acetic acid as an organic acid and cinnamon-clove beads as flavoring.

Melman teaches multi-functional dental compositions that treat dental plaque and carie formation and inhibit tooth decay and brighten/whiten teeth. The compositions of this invention comprise organic acids such as acetic acid and salts thereof, which can be combined with pharmaceutically acceptable carriers or diluents to be administered in the form of conventional dental compositions. The acetic acid is required to obtain effective inhibition of plaque and other bacteria (paragraph 0020). Other acids may be used in place of acetic acid such as ethylenediaminetetraacetic acid (paragraph 0017). Suitable flavorings include both natural and artificial flavors, and mints such as peppermint, citrus flavors such as orange and lemon, artificial vanilla, cinnamon, various fruit flavors and the like. In one embodiment the flavoring agent comprises cinnamon-clove beads. Such beads can be additionally filled with fillers consisting of inert materials or medicinal agents such as vitamins or antibacterial agents (paragraph 0037). The reference differs from the instant claims insofar as it does not teach using in

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combination with *Citrus karna*, *Zanthoxylum armatum*, *Azadirachta indica* and *Oryza sativa* in the oral care compositions.

It would have been obvious to one of ordinary skill in the art to have added acetic acid and cinnamon-clove beads in the composition of the combined teachings of the primary and secondary reference motivated by the desire to produce a toothpaste or toothpowder with effective inhibition of plaque and other bacteria properties as well as the ability to add medicants to the compositions by incorporating them into the cinnamon-clove beads, as taught by the tertiary reference.

### ***Allowable Subject Matter***

Claims 7 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the claims recite the limitation that the powdered parts or extract of *Oriza sativa* is obtained from carbon black charred husk, which in order to obtain would require a change in chemical property. This is different than practices where the essential ingredient is obtained by conventional methods of extraction or grinding the *Oriza sativa* into powder. It would be non-obvious and distinct over the art to use *Oriza sativa* in this manner.

Claims 1-6, 8-15, 32-37 and 39-47 are rejected.

Claims 7 and 38 are objected.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts  
Patent Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read "Lezah Roberts", with a long horizontal flourish extending to the right.

Frederick Krass  
Primary Examiner  
Art Unit 1614

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